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MEDICAL FOODS AND FOODS FOR SPECIAL MEDICAL PURPOSES

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OBJECTIVES: A medical food is formulated to be consumed or administered enterally under the supervision of a physician, and is intended for the specific dietary management of a disease or condition for which distinctive nutritional requirements are established by medical evaluation. In the US, medical foods are a special product category regulated by the FDA. In Europe, a similar category called "Foods for Special Medical Purposes" (FSMPs) is covered by the Foods for Particular Nutritional Uses directive and regulated by the European Commission (EC). Our objective is to review and compare the characteristics of, and regulatory environments for, medical foods and FSMPs. **METHODS:** We conducted internet and PubMed searches to identify information and guidance covering medical foods and FSMPs, including relevant FDA and EC regulations. We also reviewed and compared the characteristics, place in therapy, and potential economic impact of these products. **RESULTS:** Medical foods do not require pre-approval from the FDA for marketing. Unlike nutritional supplements, which have no disease claim and are intended for healthy individuals, medical foods must make a disease claim and are intended for use in specific diseased populations. Disease claims must be supported by sound scientific evidence substantiating claims of successful nutritional management of the disease. All ingredients must be approved food additives or classified as Generally Recognized as Safe (GRAS). Reimbursement for medical foods is inconsistent, and varies by product and by health plan. Like medical foods in the US, FSMPs are intended for use only under medical supervision, but they must comply with EC regulations. There has been little to no economic research conducted with products in these categories. **CONCLUSIONS:** Medical foods and FSMPs can play a key role in the nutritional and metabolic support of patients with certain diseases and conditions, although their economic impact has not been studied.

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ALANYL-GLUTAMINE DIPEPTIDE (DIPEPTIVEN®) IN TOTAL PARENTERAL NUTRITION (TPN) THERAPY IN CRITICALLY ILL ITALIAN PATIENTS: A PHARMACOECONOMIC SIMULATION MODEL

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OBJECTIVES: Several clinical trials have demonstrated that the supplementation of Dipeptiven® in critically ill patients in Intensive Care Units (ICUs) is associated with better clinical outcomes, **such as reduction of the infection rate, shortening of ICU** and hospital lengths of stay (LOS), and a trend toward reduced mortality, when compared to standard TPN regimens. Aim of the study is the pharmacoeconomic evaluation of Dipeptiven vs. standard TPN in critically ill patients admitted to Italian ICUs. **METHODS:** The analysis is based on a Discrete Event Simulation model that incorporates: a) baseline outcomes rates from the 2007 GIVITI report (data from 200 Italian ICUs and over 60,000 patients); b) **Dipeptiven®** efficacy from systematic review and meta-analysis with a Bayesian Random-Effects model of the published clinical trials; c) national cost data in the perspective of the hospital from published sources. The simulated clinical outcomes are: dea**th rate in ICU; infection rate in ICU; death** rate in general ward; hospital LOS, divided into LOS pre-ICU, LOS in ICU, and LOS in ward (post-ICU). One-way and probabilistic sensitivity analyses were performed and the cost/effectiveness acceptability curve generated. **RESULTS:** Dipeptiven® results more effective and less costly than standard TPN reducing mortality rate (23.55% ± 15.2% vs. 34.50% ± 2.06%), infection rate (15.91% ± 3.95% vs. 18.97% ± 3.94%), overall hospital LOS (25.47 ± **0.26 vs. 26.00** ± 0.27 days) and total cost per patient (23,922 ± **3,249 vs. 24,145** ± €3,361). This indicates that treatment cost is completely offset by the reduction in ICU costs, and by antibiotic costs for the treatment of ICU-emergent in**fections. The cost/effectiveness acceptability curve shows** that Dipepetiven® has an estimated 78% probability of resulting dominant and a 90% probability of resulting cost/effective if the decision maker is willing to pay up to €1500 to avoid one pa**tient death. CONCLUSIONS:** Dipeptiven® is expected to averagely dominate standard TPN, as it results associated with better clinical and economic outcomes.

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THE PHARMACOECONOMIC ANALYSIS OF EXTEMPORAL MEDICINES USED FOR TREATMENT OF DISEASES AT CHILDREN IN UKRAINE

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OBJECTIVES: In Ukraine the medical products made in pharmacies by extempore use wide demand, is especial for treatment of children though the quantity of the pharmacies engaged in extemporal preparation every year decreases in connection with economic conditions, features of licensing of such activity in Ukraine. Use extemporal preparations with precisely picked up concentration corresponding by the medicinal form (the suppositories, a dosed out powder) allows to provide individualized therapy of the child depending on age and weights of the body, accompanying diseases (for example a diabetes). **METHODS:** We have carried out the **ÀÂÑ- analysis** of extemporal medicines, which were prepared in pharmacies of Lviv city for 2008. **RESULTS:** Sample list of extemporal medicines has made 44 names for 2000 recipes. The dominating medicinal form solutions with precisely set concentration or features of their technological manufacturing make 45%. Also prepare for ointments (21%), dosed out powders (18%), suspensions (7%), mixtures (5%), suppositories (4%). Among medicinal forms are submitted a solution of clorhydrogenic acid with pepsinum, used for excitation of appetite at children, the recipe—Lassar paste for treatment of dermatitis at children. Such medicines are not made with a farmaceutical industry. **CONCLUSIONS:** We have defined, that costs of extemporal medicines, in particular solutions makes 4–16 UAH (1 $ = 7.7 UAH), ointments 8–27 UAH, powders of 2–6 UAN, suspension of 11–18 UAH. These extemporal medicines are economically accessible to treatment for children in Ukraine.

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COSTS OF BLEEDING RELATED COMPLICATIONS AND BLOOD PRODUCT TRANSFUSIONS AMONG SURGICAL PATIENTS

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OBJECTIVES: Inadequate surgical hemostasis may lead to bleeding related complications and transfusion. The aim of this analysis was to examine the incidence and costs of bleeding complications and blood product transfusions for patients undergoing inpatient surgeries. **METHODS:** A retrospective analysis was conducted using Premier's Perspective hospital database. Patients who had a procedure within a specialty of interest (i.e. cardiac, vascular, non-cardiac thoracic, solid organ, general, reproductive organ or knee/hip replacement) in 2006 or 2007 were identified via ICD-9 procedure codes. For each specialty, rate of bleeding complications (including bleeding event, re-operation to control for bleeding and blood product transfusions) were examined, and cost of hospitalizations and length of stay (LOS) were compared between surgeries with versus without complications. The incremental costs were based on a multivariate analysis adjusting for demographics (e.g., age, gender, geographic region), hospital characteristics (e.g., urban versus rural, bed size) and other baseline characteristics (e.g., comorbidities, admitting diagnosis, prior hospitalization). **RESULTS:** A total of 647,918 cardiac, 725,624 vascular, 227,273 non-cardiac thoracic, 139,781 solid organ, 1,586,557 general, 1,032,762 reproductive organ and 247,682 knee/hip replacement surgeries were identified. The rate of bleeding complication was highest for knee/hip replacement (29.8%), followed by vascular (27.1%), non-cardiac thoracic (26.5%), solid organ (23%), cardiac (11.7%), general (11.4%) and reproductive organ (3.3%). Incremental LOS associated with bleeding complications or transfusions was 11.5 days for non-cardiac thoracic, 10.5 days for solid organ, 10.2 days for vascular, 9.6 days for general and 1.3 days for knee/hip replacement surgeries. The incremental cost per case of hospitalization associated with complication was highest for non-cardiac thoracic surgeries ($27,069), followed by vascular ($26,272), cardiac ($20,261), solid organ ($18,420), general ($7,036), reproductive organ ($6,222) and knee/hip replacement ($3,246). **CONCLUSIONS:** This study characterizes the increased hospital LOS and cost associated with bleeding complications and transfusions, and supports implementation of blood conservation strategies.

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A SYSTEMATIC REVIEW EVALUATING COST-EFFECTIVENESS OF ACUPUNCTURE

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OBJECTIVES: Acupuncture is widely used for various diseases such as chronic low pain and osteoarthritis, but the cost-effectiveness of acupuncture has not been fully explored. The aim of this review is to summarize and assess randomized controlled trials (RCTs) of acupuncture for economic evaluation. **METHODS:** Total 5 electronic databases were searched up to May 2009 without language restrictions. The search terms used were "cost effectiveness", "cost utility" and "cost benefit" with "acupuncture". Studies presenting results of economic evaluation throughout prospective, controlled studies for any medical condition were included. The quality of study was assessed. The main outcomes for health benefit and cost were extracted and described. **RESULTS:** Thirteen RCTs that met the inclusion and exclusion criteria underwent a full-text review. Acupuncture with usual care was compared with usual care only in all studies. Nine studies were applied for pain condition including low back pain, headache, and dysmenorrhea. The reporting quality of the studies was poor for certain items. Nine studies described incremental cost-effectiveness ratio (ICER) or incremental cost per quality adjusted life year. Most studies suggested that additional acupuncture treatment was cost-effective compare to the usual care for low back pain, headache, dysmenorrhea, osteoarthritis, angina pectoris, and allergic rhinitis. **CONCLUSIONS:** This systematic review showed the cost-effectiveness of additional acupuncture treatment, but including studies were very few and applied diseases were limited. Therefore the results could not be generalized due to diversity of disease and different status of each country. The more number of economic evaluations of acupuncture are necessary to firm the evidence.

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PHARMACY STUDY OF NATURAL HEALTH PRODUCT ADVERSE REACTIONS (SONAR): ACTIVE SURVEILLANCE INCREASES AR REPORTING AND REVEALS TWO NEW INTERACTIONS

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OBJECTIVES: To implement, and assess the feasibility of an active surveillance model in community pharmacies to systematically detect adverse events (AEs) associated with the use of natural health products (NHPs) and NHP-drug interactions. **METHODS:**